1648

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Pau et al.

Serial No.: 09/449,854

Filed: November 26, 1999

For: PRODUCTION OF VACCINES

Confirmation No.: 6774

Examiner: L. Scheiner

Group Art Unit: 1648

Attorney Docket No.: 2578-4240US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10/06/2004
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

PETITION TO MAKE SPECIAL UNDER M.P.E.P. §§ 708.02 VII AND X

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Special Program Examiner for Group Art Unit 1648

Sir:

Petition

Applicants petition to make the above-referenced application related to HIV/AIDS and recombinant DNA special.

Requirements under M.P.E.P. § 708.02 X

A statement explaining how the invention contributes to the diagnosis, treatment or prevention of HIV/AIDS is transmitted herewith.

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Requirements under M.P.E.P. § 708.02 VII

A statement under 37 C.F.R. § 1.102 by the assignee explaining the relationship of the invention to safety of research in the field of recombinant DNA research is transmitted herewith.

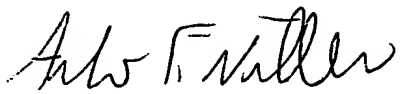
Fee

The fee required under 37 C.F.R. § 1.17(h) for each basis of the petition is to be paid by the attached check for $260.00. If the attached check is insufficient to cover the fees related to this petition, please charge any overage to Deposit Account 20-1469.

REMARKS

Consideration of this petition is respectfully requested.

Respectfully submitted,



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Date: October 6, 2004

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10/06/2004 Betty Vowles
Date Signature

Betty Vowles
Name (Type/Print)

STATEMENTS SUPPORTING PETITION TO MAKE SPECIAL UNDER M.P.E.P. §§ 708.02 VII AND X

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Special Program Examiner for Group Art Unit 1648

Sir:

Statement concerning HIV/AIDS

The above-referenced application contributes to the treatment and prevention of HIV/AIDS in that "the invention is particularly useful for the production of vaccines to aid in the protection against viral pathogens for vertebrates, in particular mammalians and especially humans." (Specification, page 1, lines 7-10). Furthermore, the specification recites "the present invention overcomes at least a number of the problems encountered with the production systems for production of viruses and/or viral proteins for vaccine purposes of the systems of the prior

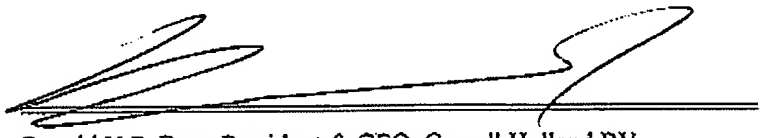
art." (*Id.* at page 2, lines 21-24). Thus, the present invention relates to the prevention of HIV/AIDS in that it eases the production of materials used for diagnostic and research purposes.

Further, the specification states "viral proteins . . . and viruses . . . or attenuated viruses that can be produced in the methods according to the invention include . . . human immunodeficiency virus." (*Id.* at page 4, line 22 through page 5, line 3). In addition to the specification, pending claim 17 expressly claims the production of human immunodeficiency virus particles or protein fragments. Thus, the as-filed specification and claim 17 of the present invention specifically contemplate the production of materials for diagnostic and research purposes for HIV/AIDS.

Statement concerning recombinant DNA

The above-referenced application relates to safety of research in the field of recombinant DNA research as it enhances the safety of vaccines and vaccine production. More specifically, the as-filed specification indicates "for reasons of safety care is best taken to avoid unnecessary sequences in the cells according to the invention. It is thus another embodiment of the invention to provide cells that do not produce adenoviral structural proteins." (*Id.* at page 3, lines 19-23).

As further stated in the specification "to have a clean and safe production system from which it is easy to recover and, if desirable, to purify the virus, it is preferred to have a method according to the invention, whereby, said human cell comprises no other adenoviral sequences." (*Id.* at page 3, lines 27-31). The specification also indicates "however, any non-human system for production of influenza vaccines has an inherent drawback, known as 'adaption'. Human influenza A and B virus both carry mutations in the HA, due to adaptation in embryonated hens' eggs. These mutations result in altered antigenicity. ... In humans, immunization with vaccines containing an HA bearing an egg-adaption induces less neutralizing antibody to virus that contains a non-egg adapted HA." (*Id.* at page 9, line 28 through page 10, line 2). Thus, the present invention relates to the field of safety in recombinant DNA technology.



October 4, 2004

Ronald H.P. Brus, President & CEO, Crucell Holland BV.